

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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Application No.: 10/687,799

Group: 1644

Filed: October 17, 2003

Examiner: Schwadron, Ronald B.

Confirmation No.: 1801

For: Human Monoclonal Antibodies Against CD20

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PETITION PURSUANT TO 37 C.F.R. § 1.181 TO VACATE THE NOTICE OF NON-COMPLIANT AMENDMENT

Director of Technology, Group 1644
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In reply to the Notice of Non-Compliant Amendment under 37 C.F.R. § 1.121 dated January 11, 2011, requesting correction of the status identifiers for the claims presented in the Amendment filed on November 3, 2010, Applicants hereby submit a Petition Pursuant to 37 C.F.R. § 1.181 to Vacate the Notice of Non-Compliant Amendment and respectfully request a review by Director of Technology of Group 1644. Although Applicants assert that the Notice of Non-Compliant Amendment is improper, and, therefore, should be vacated as discussed in detail below, a Reply to the Notice of Non-Compliant Amendment is being submitted concurrently in good faith to engage in reasonable efforts to expedite prosecution if the present Petition is found

not grantable. Request for reconsideration and withdrawal of the Notice of Non-Compliant Amendment are respectfully sought in the Reply being filed concurrently with this Petition.

ITEM 4(C) OF THE NOTICE OF NON-COMPLIANT AMENDMENT

In the Amendment submitted on November 3, 2010, Applicants provided status identifiers for all claims presented in the form of either (Cancelled), (Withdrawn), (Withdrawn-currently amended) or (New). However, in the Notice of Non-Compliant Amendment dated January 11, 2011, the Examiner indicated under ITEM 4(C) that “each claim has not been provided with the proper status identifier, as such, the individual status of each claim cannot be identified.” See Remarks of Notice of Non-Compliant Amendment under ITEM 4(C). In the note that follows the remarks, it is stated that “the status of every claim must be indicated after its claim number by using one of the following status identifiers: (Original), (Currently amended), (Canceled), (Previously presented), (New), (Not entered), (Withdrawn) and (Withdrawn-currently amended).

According to 37 C.F.R. § 1.121(c), Manner of making amendments in application, it is stated that:

(c) *Claims.* Amendments to a claim must be made by rewriting the entire claim with all changes (*e.g.*, additions and deletions) as indicated in this subsection, except when the claim is being canceled. Each amendment document that includes a change to an existing claim, cancellation of an existing claim or addition of a new claim, must include a complete listing of all claims ever presented, including the text of all pending and withdrawn claims, in the application. The claim listing, including the text of the claims, in the amendment document will serve to replace all prior versions of the claims, in the application. In the claim listing, the status of every claim must be indicated after its claim number by using one of the following identifiers in a parenthetical expression: (Original), (Currently amended), (Canceled), (Withdrawn), (Previously presented), (New), and (Not entered). 37 C.F.R. § 1.121(c); emphasis added

Applicants assert that all claims presented in the Amendment filed on November 3, 2010 comply with the requirements under 37 C.F.R. § 1.121(c) as well as ITEM 4(C) of the Notice of Non-Compliant Amendment because they were identified as either (Cancelled), (Withdrawn), (Withdrawn-currently amended) or (New). Moreover, Applicants identified in the Remarks

section of the Amendment filed on November 3, 2010 which new claims were readable on the elected species, as is deemed appropriate according to the Rules.

Therefore, Applicants respectfully request that the Notice of Non-Compliant Amendment under ITEM 4(C) be vacated and deleted from the record because all claims presented in the Amendment filed on November 3, 2010 comply with the requirements under 37 C.F.R. § 1.121(c).

ITEM 4(E) OF THE NOTICE OF NON-COMPLIANT AMENDMENT

The Examiner also indicated under ITEM 4(E) (“others”) that:

New claims drawn to nonelected species should be labeled “new, withdrawn”. The previously elected species is the 2F2 antibody as per depicted in figure 53. Claims drawn to other antibodies (aka 7D8) should be labeled “new, withdrawn”. The MPEP section 714 states: For any amendment being filed in response to a restriction or election of species requirement and any subsequent amendment, any claims which are non-elected must have the status identifier (withdrawn). See Continuation Sheet of the Notice of Non-Complaint Amendment dated January 11, 2011

However, according to MPEP § 714(F), the Notice of Non-Compliant Amendment is proper only when the Amendments fail to comply with 37 C.F.R. § 1.121. The MPEP § 714(F) states as follows:

If an amendment submitted on or after July 30, 2003, fails to comply with 37 CFR 1.121 (as revised on June 30, 2003), the Office will notify applicant by a Notice of Non-Compliant Amendment, Form PTOL-324, that the amendment fails to comply with the requirements of 37 CFR 1.121 and identify: (1) which section of the amendment is non-compliant (e.g., the amendments to the claims section); (2) items that are required for compliance (e.g., a claim listing in compliance with 37 CFR 1.121(c)); and (3) the reasons why the section of the amendment fails to comply with 37 CFR 1.121 (e.g., the status identifiers are missing). MPEP § 714 (F); emphasis added.

With respect to newly added claims, 37 C.F.R. § 1.121(c)(3) states that “any claim added by amendment must be indicated with the status of “new” and presented in clean version, i.e., without any underlining” and does not require the new claims to be identified as “new,

withdrawn” as alleged by the Examiner. With respect to withdrawn claims being amended, however, 37 C.F.R. § 1.121(c)(2) specifically requires them to be identified as “withdrawn-currently amended.” Pursuant to the Rules under 37 C.F.R. § 1.121(c), Applicants provided the status identifiers for “new” and “withdrawn-currently amended” in the Amendment filed on November 3, 2010, thus complying with all the requirements under 37 C.F.R. § 1.121(c). Because all claims presented in the Amendment comply with the requirements under 37 C.F.R. § 1.121(c), the Notice of Non-Compliant Amendment under ITEM 4(E) is inconsistent with the MPEP § 714(F).

*THE NOTICE OF NON-COMPLIANT AMENDMENT IS IMPROPER UNDER THE PTO
POLICY MEMORANDUM OF JUNE 6, 2005*

Applicants respectfully direct the Director’s attention to the USPTO Policy Memorandum of Joseph J. Rolla, Deputy Commissioner for Patent Examination Policy, dated June 6, 2005, attached hereto as Exhibit A, as evidence that issuance of the Notice of Non-Compliant Amendment for informalities in status identifiers is improper because the USPTO is waiving certain requirements set forth in 37 C.F.R. § 1.121(c) where the non-compliance is limited to “use of certain variations of status identifiers in a claim listing.” It is Applicants’ position that the Amendment filed on November 3, 2010 was in compliance with the rules, for the reasons presented herein. However, assuming *arguendo* that the Examiner’s position is correct, the Memorandum in Exhibit A should have been followed and thus the issuance of the Notice of Non-Compliant Amendment dated January 11, 2011 is improper.

REQUEST FOR EQUITABLE CONSIDERATION

Further to the arguments presented above, Applicants respectfully request, in equity, grant of this Petition to vacate the Notice of Non-Compliant Amendment of January 11, 2011 because although Applicants satisfied the requirements under 37 C.F.R. § 1.121(c), the improper Notice of Non-Compliant Amendment will adversely reduce any Patent Term Adjustment (PTA) that may be due in this application. PTA is important for the subject application because it related to a commercial product. Therefore, it would be equitable only if the improper Notice of Non-Compliant Amendment of January 11, 2011 is vacated and deleted from the record and Applicants’ rights to receive fair determination of the PTA is restored.


CONCLUSION

For the foregoing reasons, Applicants respectfully request that the Notice of Non-Compliance Amendment dated January 11, 2011 be vacated and deleted from the record and that the disposition of the newly presented claims are to be determined by the Examiner and indicated in the next Office Action on the merits.

Although it is believed that there is no fee associated with this Petition, authorization is granted to charge any fees that may be due in this matter to Deposit Account No. 08-0380.

Respectfully submitted,

HAMILTON, BROOK, SMITH & REYNOLDS, P.C.

By 

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Date: February 11, 2011

Acceptance of Certain Non-Compliant Amendments Under 37 CFR 1.121(c)

Effective immediately, the Office is waiving certain requirements set forth in 37 CFR 1.121(c) and may accept non-compliant amendments under 37 CFR 1.121(c) where the non-compliance is limited to: 1) the inclusion of text of a canceled claim, or a not entered claim, and 2) use of certain variations of status identifiers in a claim listing. The Office revised the amendment practice set forth in 37 CFR 1.121 in a final rule that became effective July 30, 2003. *See Changes to Implement Electronic Maintenance of Official Patent Application Records*, 68 Fed. Reg. 38611 (June 30, 2003), 1272 Off. Gaz. Pat. Office 197 (July 29, 2003). Although the revised amendment practice has been in effect for over 18 months, the Office is still receiving an unexpectedly high number of non-compliant amendments. Correction of the non-compliant items causes extra work for applicants, examiners and the Office's Technical Support Staff, delays prosecution and increases pendency of applications. Upon review, the Office has determined that some of the requirements of 37 CFR 1.121 are not essential and that waiver of certain provisions of 37 CFR 1.121 will still allow an examiner to clearly understand exactly what amendments have been made in an Image File Wrapper application. The Office will propose changes to 37 CFR 1.121 consistent with this notice in a rule making in due course.

37 CFR 1.121(c)(4)(i) provides that no claim text shall be presented for any claim in the claim listing with the status identifier "canceled" or "not entered." Claims that are indicated as "canceled" or "not entered" are not pending in the application and such text will be disregarded by the Office. Therefore, the Office hereby waives the provision of 37 CFR 1.121(c)(4)(i) that no claim text shall be presented for "canceled" or "not entered" claims. Accordingly, the Office will accept amendments that include the text of a canceled claim, or a not entered claim, if the amendment otherwise complies with 37 CFR 1.121, including use of the proper status identifier "canceled" or "not entered," respectively. Even though the Office will accept an amendment that includes the text of a canceled claim, or a not entered claim, applicants should comply with 37 CFR 1.121(c)(4)(i) by not providing the text of a canceled claim or a not entered claim.

37 CFR 1.121(c) provides that, in the complete claim listing of all claims ever presented, the status of every claim must be indicated after its claim number by using one of the following identifiers in parentheses: Original, Currently amended, Canceled, Withdrawn, Withdrawn-currently amended, Previously presented, New, and Not entered. Many applicants continue to use status identifiers that are not provided for in 37 CFR 1.121(c). The Office wants to reduce the burden on both the applicants and the Office and avoid delays in processing that result from holding an amendment non-compliant when the only non-compliance is the use of certain status identifiers that are not provided in 37 CFR 1.121(c) and which are determined to be clear and accurate by the Office. Therefore, the Office hereby waives the provision in 37 CFR 1.121(c) that the status of the claims must be indicated by one of the status identifiers listed in 37 CFR 1.121(c) to the extent permitted in this notice.



The Office will accept claim listings that include the alternative status identifiers set forth in the following table if the amendment otherwise complies with 37 CFR 1.121.

Table of status identifiers set forth in 37 CFR 1.121(c) and acceptable alternatives

Status Identifiers Set Forth in 37 CFR 1.121(c)	Acceptable Alternatives
1. Original	Original Claim; and Originally Filed Claim
2. Currently amended	Presently amended; and Currently amended claim
3. Canceled	Canceled without prejudice; Cancel; Cancelled; Canceled herein; Previously cancelled; Canceled claim; and Deleted
4. Withdrawn	Withdrawn from consideration; Withdrawn – new; Withdrawn claim; and Withdrawn-currently amended (see note below)
5. Previously presented	Previously amended; Previously added; Previously submitted; and Previously presented claim
6. New	Newly added; and New claim
7. Not entered	Not entered claim

Note: 37 CFR 1.121(c) sets forth that “Withdrawn-currently amended” is an acceptable variation of the status identifier “Withdrawn” for a withdrawn claim that is currently amended.

Additionally, the Office may also accept other variations of the status identifiers provided in 37 CFR 1.121(c) when the examiner determines that the status identifier used by applicant clearly and accurately designates the status of the claim.

Applicants should make every effort to comply with all of the requirements of 37 CFR 1.121, such as the use of the status identifiers provided in 37 CFR 1.121(c) in a complete claim listing, to reduce processing delays. The Office may continue to refuse to accept an amendment that does not otherwise comply with 37 CFR 1.121 or includes a status identifier which, in the opinion of the examiner, fails to clearly and accurately designate the status of a claim.

Inquiries concerning this memorandum may be directed to Elizabeth Dougherty or Eugenia Jones, Senior Legal Advisors in the Office of Patent Legal Administration, at (571) 272-7703 or PatentPractice@uspto.gov.

6/6/05
DATE

/s/
Joseph J. Rolla
Deputy Commissioner for
Patent Examination Policy